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No. 90-740

IN THE

Supreme Court of the United States

Dakota Cheese, Inc. and James Dee,
Petitioners,

v.

United States of America,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

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QUESTIONS PRESENTED

1. Can a trial judge in a criminal case partially direct a verdict against a defendant by instructing the jury that a material issue of fact has been established against the defendant as a matter of law?

2. Can it be harmless error, or consistent with due process, for a trial judge to rule at the beginning of trial that a particular issue is a factual issue for the jury, and then, after the defendant has presented its case to the jury based on that ruling, instead instruct the jury on that issue as a matter of law?

3. Where administrative regulations are so vague and undefined as to require the government to offer expert testimony at trial to establish their meaning, may the government, consistent with due process, criminally prosecute a defendant based on alleged violations of those regulations?

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OPINIONS AND ORDERS BELOW

The opinion of the court of appeals (App. A) is reported at 906 F.2d 335 (8th Cir. 1990). The order of the court of appeals denying Petitioners' petition for rehearing is unreported and is reproduced in App. B.

JURISDICTION

The court of appeals affirmed the judgment of the district court on June 13, 1990. The court of appeals denied petitioners' petition for rehearing and suggestion for rehearing *en banc* by order dated August 9, 1990. This Court has jurisdiction to review the judgment of the court of appeals by writ of certiorari pursuant to 28 U.S.C. § 1254(1).

*Dakota Cheese, Inc. has no parent company or subsidiaries.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the Sixth Amendment to the Constitution of the United States, which provides in relevant part that: "In all criminal prosecutions, the accused shall enjoy the right to a . . . trial, by an impartial jury. . . ."

This case also involves the Fifth Amendment to the Constitution of the United States, which provides in relevant part that: "No person shall . . . be deprived of life, liberty or property, without due process of law. . . ."

This case also involves the federal standards of identity for low moisture part-skim mozzarella cheese, which are codified in the Code of Federal Regulations at 21 C.F.R. § 133.156 *et seq*. The relevant regulations are reproduced in App. C.*

STATEMENT OF THE CASE

A. Introduction

The Indictment in this case charged Dakota Cheese, Inc. and James Dee, the President of Dakota Cheese, with conspiracy to defraud the United States government, mail fraud, false statements and false claims. The government alleged that Dakota Cheese sold the U.S.D.A. Commodity Credit Corporation ("CCC") low moisture part-skim mozzarella cheese that did not conform to contract specifications for the cheese. The claimed breach was novel: Dakota Cheese added pure milk protein — calcium caseinate — to the milk

*Unless otherwise indicated, all references to the regulations here are to those that were in effect in 1984 and 1985. Section 133.156 was revised effective April 11, 1988, on February 9, 1988, but this revision was after the time period relevant to the indictment.

used to manufacture the cheese. Petitioners presented evidence that the cheese met or exceeded all applicable specifications, and that government specifications explicitly allowed the addition of milk protein to the milk used to make the cheese.

At trial, both sides presented extensive expert testimony concerning the meaning of the regulations at issue. Throughout the trial both sides repeatedly stated, and the court repeatedly ruled, that the issue of whether calcium caseinate was a proper ingredient in part-skim mozzarella was a factual issue which the jury would decide. Accordingly, Dakota Cheese and Dee focused their presentation of evidence on proving to the jury that as a factual matter calcium caseinate was within the range of ingredients allowed by the regulations.

Prior to closing arguments, the trial judge informed counsel he intended to instruct the jury that, as a matter of law, the federal regulations did not allow a cheese maker to add calcium caseinate to part-skim mozzarella. Petitioners' strenuous objections were overruled, and the jury was so instructed.

At the conclusion of the two-week trial, the jury found Dakota Cheese guilty of eighteen counts: one count of conspiracy to defraud the United States in violation of 18 U.S.C. § 371; four counts of making false statements in violation of 15 U.S.C. § 714m(a); four counts of making false claims in violation of 18 U.S.C. § 287; and nine counts of mail fraud in violation of 18 U.S.C. § 1341(2). The district court fined Dakota Cheese $200,000 and placed it on unsupervised probation for one year.

James Dee was found guilty on five counts: one count of conspiracy to defraud the United States in violation of 18

U.S.C. § 371, and four counts of making false statements to the Commodity Credit Corporation in violation of 15 U.S.C. § 714m(a). Dee was fined $200,000.

Both the government at trial, and the Eighth Circuit in its opinion, rely heavily on Dakota Cheese's attempts to keep secret its use of calcium caseinate. Fully one-half of the Eighth Circuit opinion is a recitation of facts, particularly the facts relating to Dakota Cheese's furtive use of calcium caseinate. While this evidence is surely colorful, it misses the point; concealment is only relevant if calcium caseinate, as a factual matter, does not fall within the ingredients allowed by the regulations. By reversing his prior ruling and taking this issue from the jury, the judge denied petitioners both the opportunity to establish their innocence, and a fair trial. If the jury had found that calcium caseinate was within the scope of the ingredients allowed under the regulations, all the evidence of concealment would have blown away like so much smoke.

B. Background Facts

Dakota Cheese is a South Dakota Corporation that until the indictment in this action was engaged in the manufacture of mozzarella cheese. The company was indicted on various theories, all premised on alleged breach of four contracts it had with the CCC, a division of the Department of Agriculture during 1984 and 1985. Pursuant to the terms of these four contracts, Dakota Cheese was to supply the CCC with "low moisture part-skim mozzarella cheese" as defined in the standards of identity of the Food and Drug Administration ("FDA") published in the Code of Federal Regulations.

Beginning in the late 1970s and during 1982 and 1983, Dakota Cheese's President, James Dee, began a series of

innovations in the cheesemaking process, experimenting with various fortification methods for making low moisture cheese. TR 1633-36.[1] Initially he attempted fortification with nonfat dry milk, but this method did not produce a satisfactory cheese. TR 1633-38. After a substantial amount of time and expense (many production runs of cheese had to be scrapped in the process), Dee began to experiment with calcium caseinate. TR 1638, 1654-57. The use of calcium caseinate in the production of mozzarella cheese was not unheard of in the industry nor was it peculiar to Dakota Cheese. But Dee discovered a new technique and formulation that attained greater yields of a cheese of unmatched quality. TR 1654-56. That resulted, eventually, in an exclusive formula using precise proportions of whole milk, nonfat dry milk and calcium caseinate. TR 1667-68.

Mr. Dee's trial and error discovery of a formula for the addition of dry calcium caseinate along with nonfat dry milk to the milk used to make the mozzarella had a remarkable effect on Dakota Cheese's cheesemaking process. First, the use of the calcium caseinate formula resulted in greater yields, and hence the more efficient use of whole milk. TR 1949. Second, the addition of calcium caseinate allowed Dakota Cheese to add greater quantities of nonfat dry milk to the whole milk than would otherwise be possible, which improved the nutritional qualities of the cheese. TR 1940-41, 1943-47, 1949. Third, the cheese made using the calcium caseinate formula had superior physical qualities (these included meltability, stretchiness and other criteria). In sum, by entrepreneurial innovation, the formula allowed the company to "build a better mousetrap," to produce a superior cheese at less cost. TR 1948-49.

Dr. Howard Morris, a professor of Food Science at the University of Minnesota, and one of the leading authorities

[1] "TR" is a reference to the trial transcript.

in the world on cheesemaking and cheese, testified that Dee's alternative procedure for the manufacture of mozzarella cheese was an innovation that he had not seen before in his several decades of teaching and consulting, and that he wished he had thought of it himself. TR 1948. By performing a detailed analysis of the constituents of the mozzarella cheese produced by Dakota Cheese for sale to the government, Dr. Morris concluded that the Dakota Cheese low moisture part-skim mozzarella cheese was equal to or superior to every one of the United States Department of Agriculture's standards for this cheese.

Dr. Morris concluded that the Dakota Cheese low moisture part-skim mozarella cheese contained 10% more protein than the USDA standard. TR 1937. He also concluded that it contained higher quality protein (in other words, protein that meets more of the body's nutritional requirements) than the USDA standard for low moisture part-skim mozzarella. TR 1940. Mr. Dee had, in short, developed a better way to manufacture mozzarella cheese using only ingredients naturally found in mozzarella cheese itself. TR 1883-84.

It is also true that during the period that Dee was adding calcium caseinate to his cheese, he went to great lengths to conceal this fact, even from the government. Counsel for the defense admitted this fact in their opening statements, and told the jury that the evidence would show why the company had done this. TR 117-19. The government's case relied heavily on evidence of Dee's efforts to conceal Dakota Cheese's use of calcium caseinate.[2]

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[2]The evidence at trial showed that secrecy is the norm in the cheese industry. TR 632,2054. Because testimony on concealment can both fascinate and mislead, defendants asked the court for a carefully worded jury instruction that concealment alone is not illegal, and might have other explanations. Defendants' Proposed Jury Instruction No. 43. The instruction was refused. TR 2179.

Eventually, the government discovered that Dakota Cheese was fortifying its mozzarella with calcium caseinate. Dakota Cheese and Dee were indicted. Prior to trial, defendants moved to dismiss the indictment on three grounds: (1) the federal regulations were too vague to support a criminal prosecution; (2) defendants had been unconstitutionally singled out for prosecution[3]; and (3) prosecutorial misconduct. The trial court denied all motions.

A critical issue at trial was whether Dakota Cheese, by using calcium caseinate along with milk and nonfat dry milk, produced a low moisture part-skim mozzarella cheese that conformed to the contract requirements.

The specifications in question provided that:

> The cheese shipped to CCC shall be low moisture part-skim mozzarella cheese as defined by Food and Drug Administration, U.S. Department of Health, Education and Welfare in its Definitions and Standards under the Federal Food, Drug and Cosmetics Act, as amended, in effect at time of shipping.

The cheese in question is defined as "the food that is prepared from milk and other ingredients specified in this section." 21 CFR § 133.156(A).

The regulatory definitions further state what "milk" means for purposes of the definition of low moisture mozzarella:

> The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, *skim milk, nonfat dry milk, and water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.*

21 CFR § 133.156(c)(1) (emphasis added).

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[3]Defendants were the first ever prosecuted under these regulations.

The FDA regulations also define "skim milk." Skim milk, by the regulatory definition, is "milk from which sufficient milkfat has been removed to reduce its milkfat content to less than 0.5 percent." 21 CFR § 131.143(a). The definition of skim milk also provides that certain optional ingredients may be used in skim milk. These include: "Concentrated skim milk, nonfat dry milk or other *milk derived ingredients* to increase the nonfat solids content of the food: *Provided*, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients." 21 CFR § 131.143(c)(2) (italics in original; emphasis added).

At trial, Dee testified that he read the regulations, and saw that they allowed him to add skim milk to his mozzarella. TR 160. He also noticed that the regulations allowed the use of "milk-derived ingredients" in skim milk. TR 1652-53. Knowing also that calcium caseinate is a milk derived ingredient, he concluded that the regulations allowed its use in making mozzarella cheese. *Id.* Two attorneys researched the issue on Dee's behalf, and stated that they agreed with his interpretation of the regulation. TR 1494, 1600.

Dakota Cheese's trial strategy was two-pronged. First, to prove that Dee reasonably believed that the regulations allowed him to add calcium caseinate to mozzarella that Dakota Cheese supplied to the government. Second, and more importantly, Dakota Cheese intended to prove that as a factual matter, calcium caseinate fell within the regulation's definition of low moisture part-skim mozzarella.

At the beginning of trial, both sides, as well as the court, regarded the issue of whether calcium caseinate fell within

the regulatory definition of mozzarella as a factual matter for the jury.

The transcript of the trial makes clear that both the prosecution and the trial court regarded the question of what the contractual specifications permitted to be an issue of fact. In her opening statement, the prosecutor stated that she would submit expert testimony on the meaning of the FDA specifications:

> Finally we will hear evidence from an individual with the Food and Drug Administration, who will explain the development of food standards and the purpose behind them. This person will talk about the FDA standard for mozzarella cheese and *the fact that calcium caseinate is not a permitted ingredient in mozzarella cheese;* although it is permitted and specifically stated to be permitted in some other ingredients.

TR 109-10 (emphasis supplied).

Defendants moved in limine to prohibit this testimony. Defendants brought this motion because of the prosecution's remarks in her opening statement that an expert would be called to discuss the "development" and "purpose" of the cheese standards. TR 232-35. The prosecution, arguing for the admissibility of the testimony, repeatedly emphasized the factual nature of the issue:

> The *factual* part of this case is that producing cheese under the FDA standards was a specification, a *factual* specification, of the contracts between the Government and between Dakota Cheese (sic). And what is in those specifications is *factual* material that someone from the FDA is particularly able to testify about.

TR 235-36 (emphasis added).

The Court also recognized the factual nature of the issue in denying the motion in limine:

> Well, it is the view of the Court that the law, of course, applicable to the criminal violations will be given by the Court in its Instructions. *The Court views the matter of what the Food and Drug Regulations or the Department of Agriculture Regulations provide with regard to the makeup of cheese as a factual issue* which does not represent the witness giving the jurors opinions as to the guilt or innocence of the defendant. *Counsel have submitted or suggested in the opening statement that the evidence would show that the use of casein is proper and the Court views this as a factual issue and not a question of the guilt or innocence on the matter of fraud.*

TR 235-37 (emphasis added).

Both sides, and the court, maintained this view throughout the course of trial. In response to a defense motion in limine, the prosecution stated:

> We're talking about the standards that are dealt with every day in the cheese industry. The crime here is the fraud. *The crime here is the selling of this cheese to the government with the intent to defraud and part of that crime is the fact that this cheese was made not pursuant to FDA standards when those standards were Government specifications. That is a fact.* What are the specifications of the government? You have to meet them and you have to meet shipping requirements, FDA standards. *Those are all facts, what the contract specifications are and part of that is the FDA standards.*

TR 850-51 (emphasis supplied).

Defendants later moved for a judgment of acquittal pursuant to Rule 29(a) of the Federal Rules of Criminal Pro-

cedure on the grounds that the contract specifications at issue allow for the use of calcium caseinate.

The prosecution responded to these arguments by asserting that *the evidence* had demonstrated that the ingredient calcium caseinate was not a permitted ingredient in low moisture part-skim mozzarella cheese. TR 1401-02. The trial court ruled as follows on counsels' arguments:

> *It is the Court's view that the evidence presented here presents a factual dispute for resolution by the jury* as to the defendants' guilt or innocence of the offenses charged in the remaining Counts of the indictment.

TR 1403.

Despite its consistent approach to the calcium caseinate issue throughout trial, the court did an abrupt about-face when the time came to instruct the jury. Before the charge conference, the court submitted its proposed instructions to counsel. The defense was shocked to find the following proposed instruction:

> You are instructed that, as a matter of law, powdered calcium caseinate was not a permitted ingredient in the making of low moisture, part-skim mozzarella cheese at all times material to this case, under the standards of identity issued by the Food and Drug Administration and contained in the Code of Federal Regulations. . . .

Jury Instruction 13.

The court proposed this instruction on its own motion. The government, consistent with its position throughout trial, did not request the instruction. The defense strenuously objected to the proposed instruction. TR 2112. The court would not reconsider its position, and gave the instruction as originally written.

The prosecutor grabbed the unexpected opportunity with both hands. She referred to the critical sentence in Instruction No. 13 on ten separate occasions during her closing argument. TR 2219, 2231, 2233, 2243, 2247, 2256, 2342, 2343, 2344, 2351. The prosecution's repeated invocation of the judge's ruling is a succinct statement both of how closely contested the prosecution considered the underlying issue and of how critical the instruction was to the outcome of the case.

REASONS FOR GRANTING THE WRIT

I.

The Court of Appeals Established Precedent that is at Odds with Established Federal Law by Allowing the Trial Court to Direct a Verdict Against Dakota Cheese and Dee on a Material Issue of Fact.

The critical issue in a criminal prosecution is whether the defendant's conduct was unlawful. In this case, the indictment rested squarely on the premise that the use of calcium caseinate was not permitted under the applicable contract specifications. The indictment's allegations of conspiracy to defraud, fraud, mail fraud and false claims all stemmed from a root allegation: that, contrary to contract specifications, Dakota Cheese added milk protein to the milk it used to make low moisture part-skim mozzarella cheese. If calcium caseinate is permitted under the regulations, then there could be no fraud, false statement or false claim, and no count of the indictment against Mr. Dee and Dakota Cheese could stand.

The regulations set forth what ingredients could be added to mozzarella cheese. The burden was therefore upon the government to prove that the ingredients used by Dakota

Cheese were physically different from the ingredients allowed by the regulations. Likewise, Petitioners presented their expert testimony that calcium caseinate was physically identical to the ingredients listed in the regulations. The arbiter of this factual dispute should have been the jury. By taking this decision from the jury, the judge directed a verdict on the most important factual issue in the entire case.

This Court has clearly established that a trial court is prohibited from directing a verdict against a defendant in a criminal trial. *United States v. Martin Linen Supply Co.*, 430 U.S. 564, 572-73 (1977). As the Court in *Martin Linen Supply* discussed this question:

> [I]n a jury trial the primary finders of fact are the jurors. Their overriding responsibility is to stand between the accused and a potentially arbitrary or abusive government that is in command of the criminal sanction. For this reason, a trial judge is prohibited from entering a judgment of conviction or directing the jury to come forward with such a verdict . . . (citations omitted) regardless of how overwhelming the evidence may point in that direction. The trial judge is thereby barred from attempting to override the juror's independent judgment in a manner contrary to the interests of the accused.

The situation here is extremely similar to that in *United States v. White Horse*, 807 F.2d 1426 (8th Cir. 1986). In *White Horse*, the statute under which defendant was prosecuted applied only to Indian tribal organizations. *Id.* at 1428. Accordingly, the burden was on the government to prove that the organization from which defendant allegedly embezzled money was an Indian tribal organization. *Id.* The Eighth Circuit reversed defendant's conviction because the trial court instructed the jury that the facts in that case established as a matter of law that the victim organization

was an Indian tribal organization under the statute. *Id.* at 1432.

The *White Horse* court's logic is particularly compelling here. The court stated:

> The trial judge invaded the jury's domain by declaring in his instructions to the jury that, as a matter of law, the Telephone Authority constituted an Indian tribal organization under 18 U.S.C. § 1163. The judge based his determination on section 1163's definition of Indian tribal organization as interpreted in *United States v. Logan, United States v. Crossland,* and *United States v. Brame.* These cases support the conclusion that the Telephone Authority constituted an Indian tribal organization under 18 U.S.C. § 1163. The judge tween the Tribe and the Telephone Authority. *The only way the judge could have determined this nexus existed is by weighing certain evidence introduced primarily in the form of witness testimony.* The judge was thus forced to evaluate the probative value of this evidence, even if it was undisputed to reach his conclusion.

Id. at 1430 (emphases added) (citations omitted).

In this case, the conclusion is inescapable that the judge could not rule that it was illegal to add calcium caseinate, a milk-derived ingredient, to part-skim mozzarella cheese without relying on the voluminous expert testimony offered by both sides on the issue. The regulations do not refer to calcium caseinate either specifically, or in any general sense. The trial judge reached out and took the issue from the jury.[4]

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[4]In the opinion below, the court attempted to distinguish *White Horse* by stating that the issue of whether the regulations allowed the use of calcium caseinate in part-skim mozzarella was neither an element of the offense charged nor a fact essential to conviction. Dakota Cheese asserts that this is simply wrong. Each count in the indictment rested squarely on the allegation that calcium caseinate was not an ingredient permitted by the regulations in making part-skim mozzarella.

The Eighth Circuit's opinion below not only departs from its prior holding in *White Horse*, but is also at odds with the Fifth Circuit's *en banc* decision in *United States v. Johnson*, 718 F.2d 1317 (5th Cir. 1983). In *Johnson*, defendant was charged with transporting a falsely made security in interstate commerce with fraudulent intent in violation of 18 U.S.C. § 2314. The trial judge instructed the jury that as a matter of law, the Gold Certificate at issue in the case was a security. 718 F.2d at 1319. Defendant was convicted.

The Fifth Circuit, sitting *en banc*, reversed defendant's conviction. The court ruled that the issue of whether the Gold Certificates were securities was a factual issue for the jury. *Id.* at 1321 n.13. The *Johnson* court looked to both the jury trial guarantee of the sixth amendment and the due process clauses of the fifth and fourteenth amendments to reverse defendant's conviction. *Id.* at 1320.

The *Johnson* court's discussion of the difference between issues of "fact" and issues of "law" is enlightening, and applicable to petitioners' situation. The court stated:

> There is no categorical distinction between "legal" and "factual" questions, for in every case application of a legal principle turns on the presence of particular facts. * * * "Juries are always judges of the law in the sense that juries must pass on the manner and the extent in which the law expounded by the judge fits in the facts brought out in the evidence." * * * The issue is the role of the jury in the trial guaranteed to the accused.

Id. at 1321, *quoting* in part 5 McCart, Trial by Jury 116-17 (1965).

The court added that even if it were to resolve the case strictly on the "fact" and "law" distinction, it would reach the same result. The *Johnson* court reasoned:

> The definition of a security is a matter of law. It is the judge's duty to instruct the jury concerning that definition: the way in which a security is identified. Whether a particular piece of paper meets that definition, however, is for the jury to decide.

Id. at n.13.[5]

As in *Johnson*, the issue here is the role of the jury in determining each element of the crime defendant is charged with. Like *Johnson*, the trial judge in this case improperly usurped the jury's role in making that determination.

The right to a jury trial requires the right to have the jury decide all relevant issues of fact. *United States v. Voss*, 787 F.2d 393, 398 (8th Cir.) *cert. denied* 479 U.S. 888 (1986). The doctrine that forbids the trial court's use of a directed verdict in a criminal jury trial covers instructions that fall short of directing a verdict but which nonetheless have that effect. *United States v. Hayward*, 420 F.2d 142, 144 (D.C. Cir. 1969). An instruction that decides a material issue of fact as a matter of law is regarded as a prohibited partial instructed verdict of guilty. *Mims v. United States*, 375 F.2d 135, 148 (5th Cir. 1967).

A partial directed verdict against the defendant in a criminal jury trial cannot be regarded as harmless error. This Court has noted:

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[5]The *Johnson* court also noted the substantial divergence in the case law over the proper role of the judge and jury. 718 F.2d at 1322-23 n.16, 17. This "Discord in the precedents," *Id.* at 1323, is a strong reason for this Court to clarify those roles and reverse defendants' convictions.

> We have stated that "a trial judge is prohibited from entering a judgment of conviction or directing the jury to come forward with such a verdict . . . regardless of how overwhelming the evidence may point in that direction. (citations omitted). This rule stems from the Sixth Amendment's clear command to afford jury trials in serious criminal cases. (citations omitted). *Where that right is altogether denied, the State cannot contend that the deprivation was harmless because the evidence established the defendant's guilt; the error in such a case is that the wrong entity judged the defendant guilty.*

Rose v. Clark, 478 U.S. 570, 578 (1986) (emphasis added).

By denying Dakota Cheese and Dee their right to a jury trial, both courts below departed from long-established principles governing the roles of judge and jury. This may be due in part to the complex nature of the federal regulations involved. It is essential that this Court both correct the lower court's gross deviations from established principles, as well as give clear guidance to prosecutors, defendants, and courts in the proper role of the jury when criminal charges are based on complex regulations.

II.

The Trial Court's Decision to Change Its Prior Ruling After Dakota Cheese and Dee Had Presented Their Evidence Violated Due Process and Denied Dakota Cheese a Fair Trial.

The trial court's instruction on the issue of whether the contract specifications permitted the use of calcium caseinate could not have been more unfairly prejudicial to the defendants. In one critical sentence of the instructions, the court directed a verdict against the defendants on the most

vigorously contested question in the litigation, and simultaneously undermined the defense's credibility. After the defendants had argued to the jury throughout trial that the specifications permitted calcium caseinate, in reliance on rulings of the court, the court's belated reversal of its previous rulings had the effect of making it appear that the defense was attempting to mislead the jury. Even assuming, *arguendo*, that the regulations do prohibit calcium caseinate as a matter of law, it was fundamentally unfair for the court to instruct the jury contrary to its prior rulings. If the trial judge believed his previous ruling was in error, and that the calcium caseinate issue was a legal matter, he should have declared a mistrial. On retrial, the court then could have informed both sides from the outset that it considered the propriety of using calcium caseinate a legal issue, and the defense could have been conducted accordingly.

An error constitutes a denial of due process when it is so "gross," "conspicuously prejudicial" or otherwise of such magnitude that it fatally infects the trial and fails to afford the defendant the fundamental fairness that is the essence of due process. *Maggitt v. Wyrick*, 533 F.2d 383, 385 (8th Cir.) *cert. denied* 429 U.S. 898 (1976); *United States v. Polanco-Gomez*, 841 F.2d 235, 242 (8th Cir. 1988).

The defendants here relied on the court's rulings in structuring every aspect of the defense, only to learn at the close of evidence that the court had entirely changed the rules of the trial by taking defendants' most powerful defense away from the jury; the court's reversal unquestionably "fatally infected" the trial. Its early rulings induced the defendants to make the contractual propriety of the use of calcium caseinate the centerpiece of the defense; its sudden reversal swept this centerpiece away, leaving a bare table to the defense.

It is not an overstatement to say that defendants' principal trial strategy was dictated by the trial court's rulings that the contractual propriety of the use of calcium caseinate was an issue of fact for the jury. The reliance of the defendants on the trial court's rulings is plain. Both defendants posed the issue to the jury in their opening statements. All government expert witnesses were extensively cross examined by the defense to show how the regulations supported defendants' interpretation. TR 882, 918, 1003, 1045, 2044. As a result, the trial court's eventual unexplained reversal on this critical issue gutted the defense, and made the defense look of questionable integrity or intelligence (or both) in arguing to the contrary for the two weeks of trial.

Virtually all of the witnesses called by the defendants addressed the factual issue of whether the contractual terms permitted the use of calcium caseinate. In addition to George Burditt, Dr. Howard Morris and Paul Saviano, the primary remaining witnesses for the defense were Mr. Dee and two attorneys who represented him, who had researched, at his request, the issue of whether the FDA standards allow the use of calcium caseinate. Each of these witnesses addressed the issue of whether they interpreted the contract as allowing the use of calcium caseinate. TR 1113-1116, 1493-1494, 1681.

While recognizing, as it must, the error committed by the trial judge, the opinion below basically treats that error as harmless. The opinion states:

> We acknowledge the force of appellants' argument that the district court's statements made at the beginning of the trial regarding the law/fact aspect of the regulations led appellants to frame their evidence in a manner that presumed an ultimate resolution by the jury . . .

906 F.2d at 340. The opinion then states:

> Although we agree that the district court should have made its initial ruling on this point with the same clarity that it expressed at the instruction conference, we are not convinced that its failure to do so resulted in such fundamental unfairness to appellants that their convictions must be reversed.

Id.

Basically, the Eighth Circuit held that the trial court's actions amounted to harmless error. Clearly, the error was not harmless. The prejudice to defendants' case was extreme. This Court should act to overturn the dangerous precedent established by the Eighth Circuit in this case.

Besides being grossly and fundamentally unfair, the trial court's *sua sponte* jury instruction was contrary to the law of the case established in the court's previous rulings on which defendants had justifiably relied. The doctrine of the law of the case provides that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages of the same case. *Arizona v. California*, 460 U.S. 605, 618 (1983). *See Liddell v. Missouri*, 731 F.2d 1294, 1304-05 (8th Cir.) *cert. denied*, 469 U.S. 816 (1984). The rationale behind this doctrine is abundantly clear in a case such as this one, where the judge's failure to abide by his prior rulings resulted in a denial of due process to petitioners.

III.

The Regulatory Language is Unconstitutionally Vague and Could Not Have Placed Dakota Cheese or Dee on Notice that the Addition of Calcium Caseinate Was Prohibited.

Even if the government is given the benefit of every doubt as to the construction of the regulations, this prosecution, founded on the regulations, is unconstitutionally vague and exemplifies the disagreeable consequences of using the blunt instrument of the criminal process to clarify ambiguities in regulatory provisions. A criminal prosecution based on a regulatory scheme this vague and complex simply does not comport with due process.

This Court must set guidelines for criminal liability arising out of previously uninterpreted regulations. Although Dakota Cheese and Dee were the first two defendants ever prosecuted based on a violation of the regulations at issue, the due process problems presented by this prosecution are not unique.

Every day, individuals and businesses across the country who deal with the federal government attempt to act in compliance with the myriad regulations promulgated by the government. Those individuals and businesses should not be exposed to criminal liability simply because the government does not ultimately agree with their otherwise reasonable interpretations of those regulations. This Court must define what level of regulatory specificity is necessary to impose criminal liability on someone who is attempting to perform a contract with the United States.

The due process clauses of the fifth and fourteenth amendments require the government to frame its criminal prohibitions in language that is perspicuous to the average

citizen. As this Court has said: "The state may not issue commands to its citizens, under criminal sanctions, in language so vague and undefined as to afford no fair warning of what conduct might transgress them." *Raley v. Ohio,* 360 U.S. 423, 438 (1959). *See also United States v. Laub,* 385 U.S. 475, 487 (1967) ("crimes are not to be created by inference. They may not be constructed *nunc pro tunc").*

The problem of vagueness is especially prominent when the offense charged is not an historic wrong against person or property (burglary, for example, or assault), but the violation of an intricate system of administrative regulation. In *United States v. Van de Carr,* 343 F.Supp. 993 (C.D. Cal. 1972), the court acquitted a defendant who had been criminally prosecuted for violating technical regulations of the Federal Reserve Board which set margin rules pertaining to purchase of securities. The court explained its acquittal as follows:

> The trial was unique not only in the fact that it was the first criminal prosecution tried under Regulations T and U. In the experience of the court, it was also unique in that the government felt it necessary to offer expert testimony on the meaning of the Federal Reserve Board regulations. . . . If the supposed experts on the rules of regulated conduct in the employ of the government cannot agree on what is permitted and what is forbidden, it is difficult to conclude that any of the defendants could have had the requisite specific criminal intent to violate the law which is. of course, *sine qua non* of a felony.
>
> The government has vast remedial powers . . . short of the ultimate weapon of criminal prosecution for felony. It appears to this Court that it would have been more prudent for the government to have proceeded in

> this case by way of administrative remedies. The lack of clarity in the regulatory guidelines indicates that this case was, at best, a poor vehicle by which to clarify the meaning of Regulations T and U.

343 F.Supp. 1015.

This prosecution is an equally poor vehicle for clarifying the meaning of these equally opaque regulations. A person of ordinary intelligence, reading through these regulations for the first time, could not conclude with any degree of certainty that the use of this ingredient would be deemed criminal. Indeed, as in *Van de Carr*, even the government's own witnesses could not agree in their interpretations of the regulations.

To determine the validity of the standards of identity, they must be construed as a person of ordinary intelligence would interpret them. *Grayned v. City of Rockford*, 408 U.S. 104, 108-109 (1972). Because the definition of low moisture part-skim mozzarella cheese expressly allows the use of skim milk in cheese production, the inclusion of skim milk would be understood by the average person as allowed by the regulation. 21 CFR §§ 133.156, 133.158. The evidence from both government documents (Exhibit SSS) and defendants' experts made plain also that calcium caseinate could properly be added to skim milk. A person of ordinary intelligence would conclude that calcium caseinate falls squarely into the list of acceptable optional ingredients.

To claim that calcium caseinate is prohibited by regulatory language that seems to be clear, and contradictory to the claim itself, calls for an inordinately vague and convoluted construction of the regulation. The ordinary cheesemaker cannot fairly be expected to be placed on notice by

such vague promulgations. Presumably the regulatory definitions were promulgated to clarify what ingredients could be added to certain foods. But the vagueness of these definitions leaves the cheese producer without clear guidance.

The testimony at trial by industrial experts, government officials, and attorneys showed just how confusing this regulatory scheme really is. Defendants called as an expert witness Mr. George Burditt, an attorney who has specialized in food and drug law for 40 years. Mr. Burditt, who as one of the first acts of his career personally sat through all the hearings on the regulations in question, testified that in 1985 he had independently looked into the question of whether calcium caseinate could be used as an ingredient in the formulation of mozzarella cheese. TR 1201. Burditt concluded that calcium caseinate was a permitted ingredient in the cheese. TR 1213-14.

As part of his investigation, Burditt sent a letter in 1986 to the Acting Associate Commissioner of regulatory affairs of the FDA stating why Burditt believed that use of calcium caseinate was permitted under the FDA specifications. In February, 1986, the FDA responded to Burditt's letter. In its letter, the FDA conceded the following points: (1) that the cheese standards' reference to milk could technically be read to refer to the skim milk definition in Section 131.143, the same section that James Dee relied upon in his reading of the regulations; (2) that the FDA agreed that the issue was one that could cause "confusion;" and (3) that calcium caseinate could be used as an optional ingredient in skim milk. While conceding all of the above points, the letter, written in February, 1986, well after all of the events of this case, argued, based on an apparently oral "history of the cheese standards," that the skim milk definition referred only

to the definition of bottled skim milk as opposed to skim milk used for cheesemaking. Defendants introduced this letter at trial as defense Exhibit SSS.

Defendants also presented the testimony of Dr. Howard Morris and Dr. Paul Saviano, a professor of nutrition at the University of Minnesota, each of whom confirmed that all technical requirements necessary to the conclusion that the standard permitted the addition of calcium caseinate had been met. TR 1802. In particular, these two experts offered unrebutted testimony that calcium caseinate, as it was used by defendants, met the requirements that the protein efficiency ratio of the milk not be reduced. *Id.*

Dakota Cheese and Dee further provided testimony that in 1985 it requested that its attorneys research the issue of whether the standards of identity prohibited calcium caseinate. TR 1493, 1702. E. Steeves Smith and his partner, James Taylor, independently researched this issue. TR 1113, 1493. Both attorneys concluded that the regulations did not prohibit the use of calcium caseinate, and told this to Dee. TR 1494, 1600.

The testimony from the government's witnesses was confused and equivocal. There were only two barriers asserted by the government against defendants' interpretation of the contract specifications. First, the government argued that another section of the regulations, Section 130.8, states that unless an ingredient is provided for in the definition of a food it is not permitted in it. This is true enough, of course, but begs the question. As John Nichols, an FDA expert offered by the government as part of its case-in-chief, testified on cross-examination, the definition of mozzarella cheese provided for the addition of skim milk, and the only regulatory definition of skim milk provided for the use of milk-

derived ingredients, such as calcium caseinate. TR 1003, 1033-34. Unless the skim milk explicitly provided for in mozzarella is somehow different from the only skim milk definition in the rules, calcium caseinate is "provided for" in the definition of mozzarella.

This inconvenient reality led the government to make a second curious argument. The government here contended that the skim milk definition in Section 131.143 was a definition of fluid skim milk only. TR 1018-19. In other words, it was the definition of skim milk for beverage use only. TR 1018-19. This is contrary to the ordinary meaning of the general language of the specification; it was also a palpable source of confusion for the government's own experts.

This confusion was especially apparent in testimony of Dr. John Nelson, an expert offered in rebuttal by the government. Far from rebutting, Mr. Nelson instead conceded. He admitted that the definition of skim milk, as that term is used in the definition of low moisture part-skim mozzarella cheese, is located in the section 131.143 definition of skim milk, as defendants had contended. TR 2046-47. Seeing the difficulty he was now in (the door would thus be open to the addition of milk-derived ingredients like calcium caseinate to the mozzarella cheese at issue, as long as they did not affect the characteristics of the cheese) he added that, on further thought, the definition was found only in the first sentence of the general definition and not the remainder! TR 2048. The rest of the definition he inexplicably excised as irrelevant. Nelson thus agreed with defendants' analysis that the skim milk definition supplied the definition of "skim milk" as that term is used in the mozzarella standard. The government position that the regulations are

clear is hardly compelling in light of (a) the government experts' inability to agree on the source of the applicable definition of skim milk or (b) the scholastic distinctions and casuistic reasoning necessary to rationalize the prohibition of a totally milk-derived ingredient in a dairy product.

Where the regulators themselves are unable to interpret the regulations, due process prohibits the government from criminally prosecuting a defendant for allegedly violating those regulations. This Court should define what level of regulatory specificity is necessary before criminal liability may attach.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: November 6, 1990

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 89-5132

Appeals from the United States District Court for the District of South Dakota.

United States of America,

Appellee,

v.

Dakota Cheese, Inc.

Appellant.

No. 89-5133

United States of America,

Appellee,

v.

James Dee,

Appellant.

Submitted: October 12, 1989
Filed: June 13, 1990

Before LAY, Chief Judge, McMILLIAN and WOLLMAN, Circuit Judges.

WOLLMAN, Circuit Judge.

Dakota Cheese, Inc. and its president, James Dee (collectively, the appellants), appeal from convictions stemming from appellants' use of calcium caseinate in cheese that they sold to the United States Government. We affirm.

Although appellants have raised a number of issues on appeal, as might be expected following a lengthy trial in which some thirty-two witnesses testified, some in great detail about the cheese-making process in general and the ingredients used therein in particular, we discuss in detail only what we consider the two primary issues presented by the appeal.

Calcium caseinate is marketed in the United States by New Zealand Milk Products, Inc., which is owned by the dairy farmers of New Zealand through a cooperative structure. The calcium caseinate used by appellants was manufactured in New Zealand Milk Products' Sioux Falls, South Dakota, plant from casein imported from New Zealand.[2] The manufacturing process was described by Bill Twieg, the head of quality assurance and research for New Zealand Milk Products:

> In New Zealand they would start with fresh skim milk and, by use of a lactic starter culture, as you would in cottage cheese, acidify that milk down to PH4.5, which then precipitates the casein protein out of the milk. It's a process just like the cottage cheese process. Then

---

[1]The Honorable John B. Jones, United States District Judge for the District of South Dakota.

[2]Casein was described by one of appellants' witnesses as a foster protein that is one of the chief ingredients of milk. It is suspended in milk in little particles, which when precipitated (or settled out) from milk results in a curd that forms the basis for cottage cheese and other cheeses.

> after that is washed, it is dried. So, you wind up with a dry casein which is again just like a dry cottage cheese, except that it is dry and it is insoluble because the PH is low. That then is, after it is dried, is put in bags and shipped over to the U.S. to our plants here. So we would take that dry casein and convert it to caseinate by a process which just involves bringing the PH back up. Remember, I said to make casein you acidify a product until it precipitates out to get it back into solution and to make a calcium caseinate you just bring up the PH back up to neutrality, as it would be in milk, by the use of a neutralizing agent called calcium hydroxide.

Mr. Twieg then described the uses to which calcium caseinate is put:

> [T]here are many uses. The main ones I guess would be hospital diets for recovering patients, nutritional beverages, that kind of thing. Cheese substitutes and imitation cheeses, breakfast bars, these kinds of things. Some pharmaceutical preparations, protein supplements for people who need extra protein to supplement their diets and some health-food products too are made with calcium caseinates.

Indeed, New Zealand's products bulletin for calcium caseinate listed as suggested uses pharmaceutical preparations, meat emulsions, nutrition bars, imitation cheeses, and diet and health foods.

I.

Dakota Cheese is a cheese production company located in Mitchell, South Dakota. James Dee and his wife, Christine Dee, are the company's majority stockholders. From 1983 to 1985, the majority of appellants' mozzarella cheese production was sold to the United States Department of Agriculture (USDA) under contracts with the CCC, an agency of the USDA. In 1983, Dakota Cheese first started using calcium caseinate in its low moisture, part-skim mozzarella cheese that it sold to the government.

In the fall of 1983, as a result of conversations overheard in the company break room, George Sinkie, an employee of Dakota Cheese, began to question the use of calcium caseinate in the fortification of raw milk used to make cheese. Fortification consists of adding nonfat dry milk and calcium caseinate to raw milk to achieve a greater cheese yield. Sinkie telephoned the South Dakota Department of Agriculture and asked if it was legal to use calcium caseinate in cheese. Basing his response on his reading of the Code of Federal Regulations, Harold Schultz, the Department's director of dairy and egg inspection, told Sinkie that it was illegal unless the cheese was labeled as imitation. Sinkie then informed Clyde Hayen, plant foreman at Dakota Cheese, that he would no longer fortify the cheese with calcium caseinate because Dakota Cheese was not identifying its product as imitation cheese. Hayen told Sinkie that if he would not do so he should take three days off without pay. Not wanting to do something illegal, Sinkie left at the end of the week and never returned to work at Dakota Cheese.

After talking with Sinkie, Schultz asked a state inspector to investigate whether Dakota Cheese was using calcium

caseinate. No evidence was found, although Schultz checked with the inspector several times over a period of several months.

After receiving the phone call from Sinkie, Schultz also telephoned Harold Linden, regional director of the Dairy Grading Section of the USDA in Minneapolis, to inform him of the call and to check that Schultz' copy of the applicable Code of Federal Regulations was current. Linden then requested the USDA graders and inspectors to be on the lookout for calcium caseinate when they made their regular visits to Dakota Cheese and to report if they observed or became aware of its use. No such reports were received.

Dee told his employees that the use of calcium caseinate was a trade secret. He also told them that he could be in trouble if its use were known by government officials. Dee directed employees to remove the outer identifying wrapper from the calcium caseinate bags before taking them from the warehouse to the cheese making plant when state or federal inspectors were present. If bags were already at the plant, the employees were to transport the calcium caseinate from the plant back to the warehouse if inspectors were expected. Appellants directed semi-truck loads of the calcium caseinate to be removed from the warehouse before the inspectors arrived.

On one occasion, Dee drove around town looking for the inspector's car while the calcium caseinate was being loaded on a truck to remove it from the warehouse. He told employee Steven Borkowski, "I don't want to get caught with this shit." Dee also told employee Delmar Goldhammer that he didn't want the government to know about the use of calcium caseinate and that he didn't want the calcium caseinate bags "around for evidence." On one occasion,

Dee told his employees to "get rid of [the calcium caseinate] as soon as you can. If the USDA inspectors come in the plant today, they could fine * * * the hell out of me, if they seen [sic] it."

Plant foreman Clyde Hayen told employee Charles Reinhart that if Dakota Cheese ever got caught using calcium caseinate they could be fined by the government. Hayen told another employee that they would all probably lose their jobs if they got caught using calcium caseinate.

In September 1985, Mel Steffens, an auditor from the Milk Market Administrator's Office (MMA) of the USDA, conducted an audit of Dakota Cheese. Dakota Cheese had altered copies of its invoices by removing the words "calcium caseinate" in preparation for the MMA audits. In June 1986, after the MMA made repeated requests for invoices of Dakota Cheese's purchases from New Zealand Milk Products, a violation was reported to the USDA, Office of Inspector General, which led to a grand jury investigation and to the indictment.

From September 1984 through August 1985, appellants save some $695,000 on contracts worth more than $6 million by using calcium caseinate instead of nonfat dry milk.

II.

Appellants contend that the district court erred in directing a verdict on a critical issue of fact—whether calcium caseinate is permitted under the regulations—by treating the issue as a matter of law. Appellants also argue that Jury Instruction No. 13, which treats this issue as a matter of law, is contrary to the district court's prior indications that the issue would be treated as a question of fact to be determined by the jury.

The right to a jury trial includes the right to have the jury decide all relevant issues of fact. *United States v. White Horse*, 807 F.2d 1426, 1429 (8th Cir. 1986); *United States v. Voss*, 787 F.2d 393, 398 (8th Cir.), *cert. denied*, 479 U.S. 888 (1986). *See also* Fed. R. Crim. P. 30. A trial court is prohibited from directing a verdict against a defendant in a criminal trial. *United States v. Martin Linen Supply Co.*, 430 U.S. 564, 572-73 (1977). An instruction that decides a material issue of fact as a matter of law is regarded as a partial instructed verdict of guilt, *Mims v. United States*, 375 F.2d 135, 148 (5th Cir. 1967), and is prohibited. *United States v. Hayward*, 420 F.2d 142, 144 (D.C. Cir. 1969).

Over appellants' objections, the district court advised the jury in Instruction No. 13 that "as a matter of law, powdered calcium caseinate was not a permitted ingredient in the making of low moisture, part-skim mozzarella cheese at all times material to this case, under the standards of identity issued by the Food and Drug Administration and contained in the Code of Federal Regulations."

Appellants contend that the court had previously ruled that this issue was factual, citing the court's statement that:

> The Court views the matter of what the Food and Drug Regulations or the Department of Agriculture Regulations provide with regard to the makeup of cheese as a factual issue * * *.
>
> Counsel have submitted or suggested in the opening statement that the evidence would show that the use of casein is proper and the Court views this as a factual issue and not a question of the guilt or innocence on the matter of fraud.

Appellants also contend that not only did the court treat the issue as factual, the prosecutor considered the issue to be one of fact when arguing for the admissibility of testimony, as manifested by the prosecutor's statement that:

> The factual part of this case is that producing cheese under the FDA standards was a specification, a factual specification, of the contracts between the Government and between Dakota Cheese. And what is in those specifications is factual material that someone from the FDA is particularly able to testify about.

Appellants contend that they formulated their trial strategy in reliance on the references by the court and the prosecution that the issue would be treated as one of fact for the jury. Appellants further assert that virtually all of the witnesses called addressed the issue of whether the contractual terms permitted the use of calcium caseinate.

The government contends, however, that this testimony could be used by the jury to determine whether it was a reasonable interpretation under the regulations that the use of calcium caseinate was permitted. The government points out that the jury was required to find that appellants knew the use of calcium caseinate was not permitted in order to convict them. Instruction No. 13 stated in part:

> [E]ach count of the indictment includes the requirement that the *defendants acted knowingly*, that is, that they knew at the times set out in the indictment that the use of powdered calcium caseinate was not permitted by the FDA in the making of low moisture, part-skim mozzarella cheese and that the defendants knew this at the time they certified to the United States

> Department of Agriculture that the cheese sold to the Commodity Credit Corporation did comply with the requirements of the FDA. Emphasis added.)

The district court explained at the time the instructions were being settled its reasons for having admitted evidence concerning the regulations:

> Ordinarily, the Court would not permit the statutes to be presented to a jury or the Code of Federal Regulations because it is the responsibility of the Court to determine the law and set it forth in the Court's Instructions.
>
> It is the view of the Court that under the issues, as framed by the evidence in this case, the admission of the Code of Federal Regulations as they related to the definition of low fat part skim mozzarella cheese and skim milk were admitted [sic] for the purpose of determining the reasonableness of the belief set forth in the defendants' case that the use of calcium caseinate was permitted under the Code of Federal Regulations.
>
> * * * *
>
> I don't view exercising this requirement as being a directed verdict on any of the factual issues of the case, as set out by the evidence.

The present case is distinguishable from *United States v. Whitehorse*, 807 F.2d 1426 (8th Cir. 1986). In *White Horse*, we held that the district court erred in instructing the jury as a matter of law that a fact essential to conviction (whether the Indian telephone authority was a tribal organization within the meaning of the statute) had been estab-

lished by the evidence. Here, the district court did not instruct the jury on an element of the offense charged or on a fact essential to conviction. Instead, Instruction No. 13 told the jury that before appellants could be found guilty the government was required to prove beyond a reasonable doubt that appellants knew that the regulations did not permit the use of calcium caseinate in making low fat mozzarella cheese.

We acknowledge the force of appellants' argument that the district court's statements made at the beginning of the trial regarding the law/fact aspect of the regulations led appellants to frame their evidence in a manner that presumed an ultimate resolution by the jury of the question whether the regulations permitted the use of calcium caseinate. Nevertheless, much of the evidence submitted by appellants bore on the reasonableness of their belief—and thus their lack of knowledge to the contrary—that such use was permitted. Although we agree that the district court should have made its initial ruling on this point with the same clarity that it expressed at the instruction conference, we are not convinced that its failure to do so resulted in such fundamental unfairness to appellants that their convictions must be reversed. Especially are we unconvinced that the doctrine of the law of the case doctrine, *see, e.g., Arizona v. California*, 460 U.S. 605, 618 (1983), precluded the district court from ruling as it did at the close of the evidence.

III.

Appellants contend that because the evidence established that the specifications can be read to permit the use of calcium caseinate, the district court erred in denying their motions to dismiss and for judgment of acquittal.

The regulations define milk as:

> [C]ow's milk, which may be adjusted by * * * adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, and water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

21 C.F.R. § 133.156(c)(1).

Certain optional ingredients may be used in skim milk, including "concentrated skim milk, nonfat dry milk, or other milk derived ingredients." 21 C.F.R. § 131.143(c)(2). Appellants argue that because calcium caseinate is a milk derived ingredient it may be added as an optional ingredient to skim milk. As indicated above, however, 21 C.F.R. § 133.56(a) provides that mozzarella cheese is to be prepared from "milk and other ingredients specified in this section." The other ingredients listed do not include calcium caseinate. Moreover, there are other milk-derived products, including lactose from whey and whey protein concentrates, that are not permitted to be used under the regulations governing the manufacturing of cheese. In addition, the regulations on food standards in general state that a food does not conform to the definition and standard of identity if it "contains an ingredient for which no provision is made in such definition and standard." 21 C.F.R. § 130.8(a). Thus, we agree with the government that the language of the regulations is clear and that the contract specifications did not permit the use of calcium caseinate. In reaching this conclusion, we have considered the extensive evidence, expert and otherwise, submitted by appellants in support of their position to the contrary. Although much more could be written on this issue, we are satisfied that

the district court correctly interpreted the applicable regulations and specifications.

We conclude that the district court correctly ruled that as a matter of law powdered calcium caseinate was not a permitted ingredient in the making of low moisture, part-skim mozzarella cheese under the Food and Drug Administration regulations and the contract specifications. Accordingly, the district court did not err in denying the motions to dismiss and for judgment of acquittal.

Appellants raise a number of other issues that they contend require reversal. After a careful review of the record, however, we find these arguments to be without merit.

The judgment of the district court is affirmed.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS,
EIGHTH CIRCUIT.

APPENDIX B

United States Court of Appeals
FOR THE EIGHTH CIRCUIT
No. 89-5132SD

UNITED STATES OF AMERICA,

Appellee,

vs.

DAKOTA CHEESE, INC.,

Appellant.

No. 89-5233SD

UNITED STATES OF AMERICA,

Appellee,

vs.

JAMES DEE,

Appellant.

Order Denying Petition For Rehearing and Suggestion For Rehearing En Banc

Order Denying Petition For Rehearing and Suggestion For Rehearing En Banc

Appellants' suggestion for rehearing en banc has been considered by the court and is denied by reason of the lack of a majority of the active judges voting to rehear the case en banc. Judge Magill recused himself because of a conflict.

Petition for rehearing by the panel is also denied.

August 9, 1990

Order Entered at the Direction of the Court:
/s/ Robert D. St. Vrain
Clerk, U.S. Court of Appeals, Eighth Circuit.

APPENDIX C

§ 131.143 Skim milk.

(a) *Description.* Skim milk is milk from which sufficient milkfat has been removed to reduce its milkfat content to less than 0.5 percent. Skim milk that is in final package form for beverage use shall have been pasteurized or ultra-pasteurized, shall contain added vitamin A as prescribed in paragraph (b) of this section, and shall contain not less than 8¼ percent milk solids not fat. Skim milk may be homogenized.

(b) *Vitamin addition.* (1) Vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Concentrated skim milk, nonfat dry milk, or other milk derived ingredients to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(3) When one or more of the optional milk derived ingredients in paragraph (c)(2) of this section are used,

emulsifiers, stabilizers, or a combination of both, in an amount not more than 2 percent by weight of the solids in such ingredients.

(4) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(1) Milkfat content—"Fat, Roese-Gottlieb Method—Official Final Action," section 16.059.

(2) Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I — Official Final Action," section 16.032.

(3) Vitamin D content — "Vitamin D — Official Final Action," sections 43.195-43.208.

(e) *Nomenclature.* The name of the food is "Skim milk" or alternatively "Nonfat milk." The name of the food

shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase "vitamin A" or "vitamin A added", or, if vitamin D is added, the phrase "vitamins A and D" or vitamins A and D added". The word "vitamin" may be abbreviated vit.".

(ii) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(iii) The phrase "with added milk solids not fat" if the food contains not less than 10 percent milk-derived nonfat solids.

(2) The following terms may appear on the label:

(i) The word "pasteurized" if the food has been pasteurized.

(ii) The word "homogenized" if the food has been homogenized.

(f) *Label acclaration.* When used in the food, each of the ingredients specified in paragraphs (b)(2) and (c)(2), (3) and (4) of this section shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 131.143 Skim milk.

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(iii) The phrase "protein fortified" or "fortified with protein" if the food contains not less than 10 percent milk derived nonfat solids.

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§ 133.156 Low-moisture mozzarella and scamorza cheese.

(a) Low moisture mozzarella cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It may be molded into various shapes. Its moisture content is more than 45 percent but not more than 52 percent, and its milkfat content, calculated on the solids basis, is not less than 45 percent, as determined by the methods prescribed in § 133.55(a), (b), and (d).

(b) Milk which is pasteurized, and which may be clarified or homogenized or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, which may be added thereto as a starter. The milk may be acidified with vinegar. Rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to aid in setting the milk to a semisolid mass. Safe

and suitable artificial coloring to mask or neutralize any natural yellow color in the curd may be added.

The mass is cut, stirred, and allowed to stand. It may be reheated and again stirred. The whey is drained, and the curd may be cut and piled to promote further separation of whey. It may be washed with cold water and the water drained off. The curd may be collected in bundles for further drainage and ripening. The curd may be iced, it may be held under refrigeration, and it may be permitted to warm to room temperature and ripen further. The curd may be cut. It is immersed in hot water or heated with steam and is kneaded and stretched until smooth and free of lumps. Then it is cut and molded. In molding, the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is firmed by immersion in cold water and may be salted in brine and drained.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, and water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145 degrees F for a period of 30 minutes or for a time and temperature equivalent thereto in phosphatase destruction. The finished food shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.5(c).

(d) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the cheese during the kneading and stretching process and/or applied to the surface of the cheese.

(e) Nomenclature: The name of the food is "low moisture mozzarella cheese" or alternatively, "low moisture scamorza cheese".

(f) Label declaration: The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes". Pursuant to section 403(k) of the Federal Food, Drugs, and Cosmetic Act (21 U.S.C. 343(k), artificial color need not be declared, except as required by § 101.22(c) of this chapter. Voluntary declaration of such color in cheese is recommended.

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(b) Milk, which is pasteurized, and which may be clarified or homogenized or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, which may be added thereto as starter. The milk may be acidified with vinegar. Rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to aid in setting the milk to a semisolid mass. The mass is cut, stirred, and allowed to stand. It may be reheated

and again stirred. The whey is drained, and the curd may be cut and piled to promote further separation of whey. It may be washed with cold water and the water drained off. The curd may be collected in bundles for further drainage and ripening. The curd may be iced, it may be held under refrigeration, and it may be permitted to warm to room temperature and ripen further. The curd may be cut. It is immersed in hot water or heated with steam and is kneaded and stretched until smooth and free of lumps. When it is cut and molded. In molding, the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is firmed by immersion in cold water and may be salted in brine and drained.

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(d) Safe and suitable antimycotic agent(s) may be added to the cheese during the kneading and stretching process or applied to the surface of cut, sliced, diced, and/or shredded forms.

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(f) Label declaration of ingredients: Each of the ingredients used in the food shall be declared on the label as required by applicable sections of Part 101 of this chapter.

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§ 133.157 Part-skim mozzarella and scamorza cheese.

Part-skim mozzarella cheese, part-skim scamorza cheese conforms to the definition and standard of identify as prescribed for mozzarella cheese by § 133.155, except that its milk fat content, calculated on the solids basis, is less than 45 percent but not less than 30 percent.